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09/965,740	09/28/2001	Christopher D. Batich	QMT1.1-CIP-US	4440

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EXAMINER

ANDERSON, CATHARINE L

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/965,740	Applicant(s) BATICH ET AL.	
	Examiner C. Lynne Anderson	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-17,19-31,33-46 and 51-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-17,19-31,33-46 and 51-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: <u>20070726</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-2, 4-17, 19-31, 33-46, 51-69 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-17, 19-31, 33-46, 51-53, 56-58, 66, and 68-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson (5,783,502) in view of Sherba et al. (EP 0 493 970).

With respect to claims 1, 30, and 51, Swanson discloses all aspects of the claimed invention with the exception of the quaternary ammonium structure not being pendant to the main chain of the polymer. Swanson discloses a material capable of absorbing biological fluids comprising a flexible substrate and an enhanced surface, as disclosed in column 1, lines 9-15. The enhanced surface comprises a polymer of monomeric moieties comprising a quaternary ammonium, as disclosed in column 5, lines 34-53, as a pendant group. The polymer is covalently bonded to the flexible substrate, as disclosed in column 2, lines 45-48, and is therefore non-hydrolyzable and non-leachable.

Sherba teaches the use of a polymer comprising a quaternary ammonium structure for use as an antimicrobial, as disclosed on page 3, lines 21-22, where the quaternary ammonium structure is part of the polymer chain backbone, as shown on page 3, lines 25-35. The polymers of Sherba are useful for protecting textiles, as disclosed on page 5, lines 1-2. The polymers provide greater antimicrobial protection because they do not lose activity, as disclosed on page 5, lines 28-29.

It would therefore be obvious to one of ordinary skill in the art to provide the enhanced surface of Swanson with the polymers taught by Sherba, having the quaternary ammonium structure not pentant, to provide improved antimicrobial protection.

With respect to claims 2 and 31, the monomeric moieties comprise a quaternary ammonium, as disclosed in column 5, lines 34-53.

With respect to claim 5, the polymer is completely polymerized, and therefore has a degree of polymerization of 100.

With respect to claims 6 and 34, the material comprises part of a wound dressing, sponge, or surgical gown, as disclosed in column 1, lines 9-10.

With respect to claims 7 and 35, the flexible substrate is naturally derived, as disclosed in column 4, lines 16-17.

With respect to claims 8 and 36, the flexible substrate is synthetic, as disclosed in column 4, lines 16-17.

With respect to claims 9 and 37, the polymer is bonded to the flexible substrate by an ether linkage, as disclosed in the table on column 9, and column 9, lines 7-8.

With respect to claim 10, the claim is drawn to the final product of the absorbent material. The method of forming the covalent bond between the substrate and polymer is considered a product-by-process limitation. Therefore, the claim is anticipated by the absorbent material of Swanson that exhibits all the structural limitations of the final product.

With respect to claims 11 and 39, the polymer is formed from vinyl-containing monomers, as disclosed in column 5, lines 53-55.

With respect to claims 12 and 40, the monomers are ammonium salts, as disclosed in column 5, lines 57-62.

With respect to claims 13 and 41, the monomers are methacrylamides, as disclosed in column 5, lines 57-62.

With respect to claims 14 and 42, the monomers are vinyl pyridine derivatives, as disclosed in column 5, lines 53-55.

With respect to claims 52, 66, and 73-75, the monomeric moieties are bound by covalent bonds comprising carbon-carbon, carbon-oxygen, and carbon-nitrogen bonds, as shown in column 5.

With respect to claims 53, 58, 68, and 69, the flexible substrate may be woven or nonwoven, as disclosed in column 4, lines 10-25.

With respect to claim 56, Swanson discloses all aspects of the claimed invention with the exception of a hemostatic agent. The use of hemostatic agents in wound dressings to inhibit bleeding are well known in the art. It would therefore be obvious to

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one of ordinary skill in the art at the time of invention to provide the material of Swanson with a hemostatic agent to inhibit bleeding.

With respect to claims 70-73, the polymer of Sherba is a homopolymer, as disclosed on page 3, lines 25-35.

With respect to claims 76-78, the claims further limit an element of the Markush groups of claims 14, 28, and 42 not relied upon in the rejection. Therefore, since Swanson discloses a different element of the Markush groups, the claims are still anticipated by Swanson.

Claims 4 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson (5,783,502) in view of Sherba et al. (EP 0 493 970), and further in view of Mao (6,346,125).

Swanson, as modified by Sherba, discloses all aspects of the claimed invention with the exception of the moieties comprising a biguanide. Mao discloses a material for absorbing fluids comprising a flexible substrate having an enhanced area comprising a polymer of antimicrobial monomeric moieties, as disclosed in column 1, lines 5-8. The flexible substrate comprises a nonwoven fabric of cellulose or synthetic fibers, as disclosed in column 9, lines 1-9. The antimicrobial may be a biguanide, as disclosed in column 4, lines 42-46. The treatment of the substrate with a quaternary compound or biguanide provides the fabric with improved inhibition of microorganisms and odors, as disclosed in column 9, lines 20-24. It would therefore be obvious to one of ordinary skill in the art at the time of invention to treat the flexible substrate of Swanson with a

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biguanide, as taught by Mao, to provide the fabric with improved inhibition of microorganisms and odors.

Claims 15, 43-46, 54, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson (5,783,502) in view of Sherba et al. (EP 0 493 970), and further in view of Kolb et al. (6,797,856).

Swanson, as modified by Sherba, fails to disclose dimethyldiallylammonium chloride (DADMAC). Kolb teaches the use of quaternary ammonium and DADMAC as equivalent compounds in the treatment of an absorbent material for antimicrobial purposes, as disclosed in column 6, lines 16-33. It would therefore be obvious to one of ordinary skill in the art at the time of invention to treat the flexible substrate of Swanson with dimethyldiallylammonium chloride, as taught by Kolb, since it is functionally equivalent to quaternary ammonium.

With respect to claims 44-46, the flexible substrate of Swanson comprises cellulose, a wood fiber, or synthetic polymers, as disclosed in column 4, lines 10-25.

Claims 16-17, 20-28, 59-60, and 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson (5,783,502) in view of Sherba et al. (EP 0 493 970), and further in view of Baker (5,643,238).

Swanson, as modified by Sherba, discloses all aspects of the claimed invention with the exception of superabsorbent material capable of absorbing at least 30 times its weight of water. Swanson discloses in column 5, lines 53-55, the polymer is

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polyacrylamide. Baker discloses in column 6, lines 29-34, that polyacrylamide is a superabsorbent polymer. Swanson, as evidenced by Baker, therefore discloses a superabsorbent material. It would have been obvious to one of ordinary skill in the art at the time of invention to make the superabsorbent material of Swanson capable of absorbing at least 30 times its weight in water, since it has been held that where the general conditions (i.e. absorption of body fluids by a sponge or drape) of the claim are disclosed in the prior art, finding the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claim 17, the monomeric moieties comprise a quaternary ammonium, as disclosed in column 5, lines 34-53.

With respect to claim 20, the material comprises part of a wound dressing, sponge, or surgical gown, as disclosed in column 1, lines 9-10.

With respect to claim 21, the flexible substrate is naturally derived, as disclosed in column 4, lines 16-17.

With respect to claim 22, the flexible substrate is synthetic, as disclosed in column 4, lines 16-17.

With respect to claim 23, the polymer is bonded to the flexible substrate by an ether linkage, as disclosed in the table on column 9, and column 9, lines 7-8.

With respect to claim 24, the claim is drawn to the final product of the absorbent material. The method of forming the covalent bond between the substrate and polymer is considered a product-by-process limitation. Therefore, the claim is anticipated by the

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absorbent material of Swanson that exhibits all the structural limitations of the final product.

With respect to claim 25, the polymer is formed from vinyl-containing monomers, as disclosed in column 5, lines 53-55.

With respect to claim 26, the monomers are ammonium salts, as disclosed in column 5, lines 57-62.

With respect to claim 27, the monomers are methacrylamides, as disclosed in column 5, lines 57-62.

With respect to claim 28, the monomers are vinyl pyridine derivatives, as disclosed in column 5, lines 53-55.

With respect to claim 59, the monomeric moieties are bound by covalent bonds comprising carbon-carbon, carbon-oxygen, and carbon-nitrogen bonds, as shown in column 5.

With respect to claims 60 and 65, the flexible substrate may be woven or nonwoven, as disclosed in column 4, lines 10-25.

With respect to claim 64, the flexible substrate is nylon or polyester, as disclosed in column 4, lines 15-18.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson (5,783,502) in view of Sherba et al. (EP 0 493 970) and Baker (5,643,238), as applied to claim 16 above, and further in view of Mao (6,346,125).

Swanson, as modified by Sherba and Baker, discloses all aspects of the claimed invention with the exception of the moieties comprising a biguanide. Mao discloses a material for absorbing fluids comprising a flexible substrate having an enhanced area comprising a polymer of antimicrobial monomeric moieties, as disclosed in column 1, lines 5-8. The flexible substrate comprises a nonwoven fabric of cellulose or synthetic fibers, as disclosed in column 9, lines 1-9. The antimicrobial may be a biguanide, as disclosed in column 4, lines 42-46. The treatment of the substrate with a quaternary compound or biguanide provides the fabric with improved inhibition of microorganisms and odors, as disclosed in column 9, lines 20-24. It would therefore be obvious to one of ordinary skill in the art at the time of invention to treat the flexible substrate of Swanson with a biguanide, as taught by Mao, to provide the fabric with improved inhibition of microorganisms and odors.

Claims 29 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson (5,783,502) in view of Sherba et al. (EP 0 493 970) and Baker (5,643,238), as applied to claim 16 above, and further in view of Kolb et al. (6,797,856).

Swanson, as modified by Sherba and Baker, fails to disclose dimethyldiallylammonium chloride (DADMAC). Kolb teaches the use of quaternary ammonium and DADMAC as equivalent compounds in the treatment of an absorbent material for antimicrobial purposes, as disclosed in column 6, lines 16-33. It would therefore be obvious to one of ordinary skill in the art at the time of invention to treat the

flexible substrate of Swanson with dimethyldiallylammonium chloride, as taught by Kolb, since it is functionally equivalent to quaternary ammonium.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson (5,783,502) in view of Sherba et al. (EP 0 493 970), and further in view of Faries, Jr., et al (5,816,252).

Swanson, as modified by Sherba, discloses all aspects of the claimed invention with the exception of an indicator. Faries teaches the use of an indicator in a surgical drape to alert to the presence of leaks, as disclosed in column 2, line 65 to column 3, line 3. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the material of Swanson with an indicator, as taught by Faries, to alert to the presence of leaks.

Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson (5,783,502) in view of Sherba et al. (EP 0 493 970) and Baker (5,643,238), as applied to claim 16 above, and further in view of Faries, Jr., et al (5,816,252).

Swanson, as modified by Sherba and Baker, discloses all aspects of the claimed invention with the exception of an indicator. Faries teaches the use of an indicator in a surgical drape to alert to the presence of leaks, as disclosed in column 2, line 65 to column 3, line 3. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the material of Swanson with an indicator, as taught by Faries, to alert to the presence of leaks.

Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson (5,783,502) in view of Sherba et al. (EP 0 493 970) and Baker (5,643,238), as applied to claim 16 above.

Swanson, as modified by Sherba and Baker, discloses all aspects of the claimed invention with the exception of a hemostatic agent. The use of hemostatic agents in wound dressings to inhibit bleeding are well known in the art. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the material of Swanson with a hemostatic agent to inhibit bleeding.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 4,137,217 discloses polymers having a quaternary ammonium structure that is not pentant to the polymer.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number is (571) 272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CMA
cla
November 7, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

